PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

BECKHAM, Robert William
D/PR Formalities Section
Poplar 2
MOD Abbey Wood 2218
Bristol BS34 8JH
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	28.12.2004
Applicant's or agent's file reference: P1339/WOD	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 03/04291	02.10.2003	03.10.2002

Applicant: THE SECRETARY OF STATE FOR DEFENCE et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Vilz, B Tel. +49 89 2399-2292

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P1339/WOD	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/04291	International filing date *(day/month/year)* 02.10.2003	Priority date *(day/month/year)* 03.10.2002
International Patent Classification (IPC) or both national classification and IPC G01N1/00		
Applicant THE SECRETARY OF STATE FOR DEFENCE et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22.04.2004	28.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Timonen, T Telephone No. +49 89 2399-5666

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/04291

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-23 as originally filed

Claims, Numbers

1-18 received on 25.09.2004 with letter of 15.09.2004

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 8,9

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 8,9 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-18
	No:	Claims	
Inventive step (IS)	Yes:	Claims	11,12,14-18
	No:	Claims	1-10,13
Industrial applicability (IA)	Yes:	Claims	1-18
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

1. No opinion as to novelty, inventive step or industrial application of the subject-matter of claims 8 and 9 is given as the subject-matter of these claims does not fulfill the requirements of Article 6 PCT with respect to clarity. (See paragraphs 7.3 and 7.4 for reasons.)

Re Item V

2. Reference is made to the following document:

   D1: EP 0 010 965

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

   Document D1, which is regarded as the closest prior art, discloses

   - *a method suitable for isolating a known volume of sample solution,* see page 1, paragraph 1, *comprising*
   - *taking an apparatus comprising a first chamber* (1) *with a sealing means* (9), *a second chamber* (6), see Figure 1, *wherein*
   - *said first and said second chamber are connected via a duct* (2) *and collecting the sample solution into the first chamber of the apparatus,* see Figure 1 and page 4, paragraph 1*; and*
   - *pumping a pre-determined known volume of the sample solution into the second chamber of the apparatus,* see page 4, paragraph 2.

   The subject-matter of claim 1 differs from that disclosed in the closest prior art in defining that the sample solution comprises a nucleic acid target material.

   As the method suitable for isolating a known volume of sample solution is known , the person skilled in the art would consider using the method known from D1 with sample

solutions comprising a nucleic acid target material without having to exercise any inventive activity.

Hence, the subject-matter of claim 1 does not appear to fulfill the requirements of Article 33(3) PCT.

4. Furthermore, the subject-matter of dependent claims 2-7 and 10 does not contain an inventive step in the sense of Article 33(3) PCT.

4.1 Claims 2, 3, 7 and 10 do not add anything of inventive significance to the subject-matter of the independent claim 1, since their subject-matter has already been disclosed in document D1.

Claim 2: In the apparatus according to D1 the duct extends upwardly externally from an inlet (3) in the bottom of the first chamber to an inlet (7) in the top of the second chamber, see Figure 1 and page 2, paragraph 2.

Claim 3: The apparatus according to D1 is manufactured from a moulded resiliently deformable plastic, see claim 2.

Claim 7: The amount of liquid to be isolated in the second chamber of the apparatus according to D1 has a volume of 10-30 ml, see page 1, lines 3-7.

Claim 10: The apparatus according to D1 is a plastic container and thus disposable.

4.2 Altering the volume of the chambers and the duct is workshop modification which requires no inventive skill and results in no further technical effect. Therefore, the subject-matter of claims 4-6 would not appear to be inventive.

5. Furthermore, the subject-matter of claim 13 does not appear to be inventive in the sense of Article 33(3) PCT, for the following reasons:

Document D1, which is regarded as the closest prior art, discloses (see Figure 1)

- *an apparatus suitable for isolating a known volume of sample solution,* see page 1, paragraph 1, *comprising*
- *a first chamber* (1) *with an opening* (8);
- *a second chamber* (6) *with an opening* (10);
- *a means for sealing said first chamber* (9);
- *a means for sealing said second chamber* (11); *wherein*
- *the first chamber is connected to the second chamber by a duct* (2).

The subject-matter of claim 13 differs from document D1 in defining that the means for sealing the second chamber have an inverted conical shape. This feature does not appear to solve any technical problems and appears to be merely a design option with no apparent further technical effect. Therefore, the subject-matter of claim 13 would not appear to be inventive.

6. The subject-matter of independent claims 11, 14 and 18 would appear to be neither known nor rendered obvious by the available prior art. Although the method and apparatus suitable for separating a known volume of sample solution is known, the prior art gives no indications that would guide the person skilled in the art to place the sample in the second chamber of the apparatus and use a known amount of solvent or to place a functional reagent in the second chamber of the apparatus.

6.1 Claims 12 and 15-17 are dependent on claims 11 and 14 respectively and as such also meet the requirements of the PCT with respect to novelty and inventive step.

7. Observations on the form and content of the application

7.1 Although claims 14 and 18 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter. The

aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

7.2 The term *"about"* used in claims 4-8 is vague and renders the definition of the subject-matter of said claims unclear (Article 6 PCT). Furthermore, the repetitive use of "preferably" in connection with several volume ranges listed renders the intended scope of protection (actual range for which protection is sought) unclear.

7.3 Claim 8 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. At present the claim attempts to define the subject-matter by stating a wish for a result to be achieved instead of clearly defining those technical features or steps which are necessary for carrying out the invention.

7.4 Claim 9 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined, since the expression *"...the first chamber of the apparatus integrates with a funnel."* leaves the skilled person in doubt as how to integrate the chamber with a funnel.

7.5 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

7.6 The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

7.7 Independent claims 13, 14 and 18 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

CLAIMS

1. A method for isolating a known volume of sample solution comprising:

   (i) taking an apparatus comprising a first chamber with a sealing means, a second chamber, wherein said first and said second chamber are connected via a duct and collecting the sample solution into the first chamber of the apparatus; and

   (ii) pumping a pre-determined known volume of the sample solution into the second chamber of the apparatus.

   characterised in that the sample solution comprises a nucleic acid target material.

2. A method according to Claim 1 wherein, when the apparatus is upright, the duct extends upwardly externally from an inlet in the bottom of the first chamber to an inlet in the top of the second chamber.

3. A method according to any of Claim 1 or 2 wherein the apparatus is manufactured from a moulded resiliently deformable plastic.

4. A method according to any of Claims 1 to 3 wherein the first chamber of the apparatus has a volume of from about 1ml to about 500ml, preferably of from about 10ml to about 100ml and more preferably of from about 20ml to about 50ml.

5. A method according to any of Claims 1 to 4 wherein the second chamber of the apparatus has a volume of from about 1ml to about 100ml, preferably of from about 2ml to about 50ml and more preferably of from about 5ml to about 30ml.

6. A method according to any of Claims 1 to 5 wherein the duct has a volume of from about 0.1ml to about 5ml, preferably from about 1ml to about 3ml.

7. A method according to any of Claims 1 to 6 wherein the volume of sample solution to be isolated in the second chamber is pre-determined to be from about

1ml to about 50ml, preferably from about 2ml to about 30ml and more preferably from about 5ml to about 20ml in the second chamber.

8. A method according to any of Claims 1 to 7 wherein the volume of sample solution isolated in the second chamber is accurate to within about 10%, preferably less than about 5% and more preferably less than about 1% of said pre-determined volume.
9. A method according to any of Claims 1 to 8 wherein the first chamber of the apparatus integrates with a funnel.
10. A method according to any of Claims 1 to 9 wherein the apparatus is disposable.
11. A method for isolating a known volume of sample solution comprising:
    (i) taking an apparatus comprising a first chamber with a sealing means, a second chamber, and wherein said first and said second chamber are connected via a duct and placing a sample into the second chamber of the apparatus;
    (ii) placing a solvent suitable for dissolving or diluting said sample into the first chamber of the apparatus;
    (iii) pumping a pre-determined known volume of said solvent from the first chamber into the second chamber of the apparatus; and
    (iv) allowing said solvent to dissolve or dilute said sample.
12. A method according to Claim 11 wherein the sample is a solid or viscous liquid sample.
13. An apparatus for isolating a known volume of sample solution comprising:
    (i) a first chamber with an opening;
    (ii) a second chamber with an opening;
    (iii) a means for sealing said first chamber;

(iv) a means for sealing said second chamber said means having an inverted conical shape; and

wherein the first chamber is connected to the second chamber by a duct.

14. An apparatus for isolating a known volume of sample solution comprising:

(i) a first chamber with an opening;

(ii) a second chamber with an opening said chamber additionally comprising a functional reagent;

(iii) a means for sealing said first chamber; and

wherein the first chamber is connected to the second chamber by a duct.

15. An apparatus according to Claim 14 wherein the functional reagent is a pre-dosed reagent bead capable of lysing bacteria.

16. An apparatus according to Claim 15 wherein the functional reagent comprises chaotrophic salts.

17. An apparatus according to Claim 14 or 15 wherein the functional reagent comprises a control nucleic acid sequence.

18. A kit for isolating a known volume of sample solution comprising:

(i) an apparatus comprising:

(a) a first chamber with an opening;

(b) a second chamber with an opening;

(c) a means for sealing said first chamber; and

wherein the first chamber is connected to the second chamber by a duct, and

(ii) a functional reagent.